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ENGLISH TRANSLATION
OF THE ANNEXES TO THE
INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

Translation

PATENT COOPERATION TREATY

PCT/CH2002/000706



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1983/PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/CH2002/000706	International filing date (day/month/year) 17 December 2002 (17.12.2002)	Priority date (day/month/year)
International Patent Classification (IPC) or national classification and IPC A61F 2/44		
Applicant MATHYS MEDIZINALTECHNIK AG		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 28 June 2004 (28.06.2004)	Date of completion of this report 21 April 2005 (21.04.2005)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/CH2002/000706

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
 pages 1-9, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages 1-18, filed with the letter of 18 March 2005 (18.03.2005)
- ☒ the drawings:
 pages 1-4, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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International application No.
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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 17, 18

because:

☒ the said international application, or the said claims Nos. 17, 18
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See the supplemental sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 17, 18

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: BOX III.1

Non-establishment of opinion with regard to novelty,
inventive step and industrial applicability

Claims 17 and 18 relate to subject matter which, in the
opinion of this Authority, falls under PCT Rule 67.1(iv).
Consequently, no opinion is established with regard to
the industrial applicability of the subject matter of
these claims (PCT Article 34(4)(a)(i)).

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-16	YES
	Claims		NO
Inventive step (IS)	Claims	1-16	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-16	YES
	Claims		NO

2. Citations and explanations

This report makes reference to the following documents:

- D1: WO 99/59492 A (FRIGG ROBERT; SYNTHES AG (CH); SYNTHES USA (US)), 25 November 1999 (1999-11-25)
- D2: US 2002/052656 A1 (MICHELSON GARY KARLIN), 2 May 2002 (2002-05-02)
- D3: WO 01/15638 A1 (CAUTHEN RESEARCH GROUP, INC.), 8 March 2001 (2001-03-08)

Document D3 was not cited in the international search report.

- Document D1 is considered to constitute the prior art closest to the subject matter of claim 1 and discloses (the references in parentheses are to that document; see figures 6-8 and page 15, paragraph 2 - page 16, paragraph 1):

an intervertebral implant (38), in particular an artificial intervertebral disk, having a central axis, a top plate (61) suitable for supporting the base plate of an overlying vertebra, and a bottom plate (61) suitable for supporting the covering plate of an underlying vertebra, in which implant

- (A) the top plate (61) has a ventral side surface, a dorsal side surface, two lateral side surfaces, an upper apposition surface and a lower surface;
- (B) the bottom plate (61) has a ventral side surface, a dorsal side surface, two lateral side surfaces, a lower apposition surface and an upper surface;
- (C) the two plates (61) are movable relative to one another by means of two articulations (10) arranged between the two plates (61), and
- (D) each of the articulations has a rotational axis (5, 15) and the two rotational axes (5, 15) extend transversely to one another;
- (E) the two articulations comprise an upper piece joined to the upper plate (61) (connection pin on the inner side of 61 at 15), a central articulation piece (16) and a lower articulation piece (4, 60) joined to the lower plate (61),
- (F) the central articulation piece (16) being rotatably joined about the rotational axis (5) to the lower articulation piece (4, 60) by means of at least one axis that is coaxial to the rotational axis (5) and being rotatably joined about the rotational axis (15) to the upper articulation piece by means of at least one axis that is coaxial to the rotational axis (15).

The subject matter of claim 1 therefore differs from the known intervertebral implant in that means designed as an insert are provided whose upper and lower ends can be inserted each into a recess of the upper and lower pieces in order to temporarily block the mobility of the two pieces about the articulation.

The subject matter of claim 1 is therefore novel (PCT Article 33(2)).

- 1.1 The present invention can therefore be considered to address the problem of temporarily blocking the intervertebral implant using blocking means which can be safely and easily inserted into their precisely defined position during implantation.

The solution to this problem, as proposed in claim 1 of the present application, involves an inventive step (PCT Article 33(3)) because it is not obvious and is not suggested by any of the search report citations. Although D3 describes means for blocking an intervertebral implant, it does not mention any guiding means as defined in claim 1, which make it possible to position the blocking means in an easy, safe and precise manner.

2. Claims 2-16 are dependent on claim 1 and therefore also meet the PCT novelty and inventive step requirements.